G2B

Increase Focus

Inspection Approach

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2B (Activity 1)	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, "Did the QSIT focus on the key elements of your quali system? Yes [ ] No [ ] If Yes, how did this focus prove beneficial to your firm? Please give examples." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that the QSIT focused on the key Quality System elements.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct and objective measurement on whether the QSIT approach focused the key Quality System elements. It does not directly compare QSIT to the current FDA auditing technique	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.	

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G2B	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the QSIT focused on the key Quality System elements.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: "Did the QSIT focus on the key elements of your quality system? Yes [ ] No [ ] If yes, how did this focus prove beneficial to your firm? Please give examples." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 19 (100%)	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G2B (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Did the QSIT focus on the key elements of your quality system? Yes [ ] No [ ]
If yes, how did this focus prove beneficial to your firm? Please give examples.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			We focused on the CAPA section that demonstrated that we actively corrected problems.
2	X			It provided an independent audit to locate shortcomings.
3	X			Findings resulted in improved procedures and processes. Better understanding of Design Controls. Streamlined Management Controls process.
4	X			It focused on key elements (i.e., Management Controls, Design Controls, Corrective and preventive Actions, and Production and Process controls) and thus limited the length of the investigation based on those elements.
5	X			It allowed us to pull the appropriate documents quicker with less confusion on the direction the audit was moving.
6	X			QSIT seems more concerned with the processes resulting in a product rather than a hunt for paperwork errors.
7	X			Provided clear focus for the investigation and help provide insight in areas of improvement for the firm.
8	X			Design Control is the most beneficial to us.
9	X			
10	X			It provided a more meaningful audit of the system than the 'bottom up' approach, and covered more items in a shorter timeframe. We feel we had a thorough audit that covered all subsystems.
11	X			Reinforced the areas that quality system is based on – our doc. system is based around these areas – same areas as other reg. Bodies focus on as well as internal audits.
12	X			It immediately directed us to areas we need to improve. The auditor knew we were insufficient in our written Quality Policy Statement and designated responsible individual.
13	X			Concentration on 4 key quality systems – concentration on system integrity & information analysis – review of CPA database
14	X			It helped us prepare specific documentation. Inspection conducted without surprises. Enabled us to make available specific technical support.
15	X			The auditor told me exactly what points she was going to review – so I had them assembled.
16	X			The QSIT did focus on the key elements, however, it had neither a positive nor negative effect on the inspection.
17	X			The focus helped in scheduling personnel to be available, and in giving us a good review of our system procedures.
18	X			Our Quality System is structured as a complete system so the inspection focus was well matched with our implementation.
19	X			This approach challenged the main quality systems and how they work together.
TOTAL	19	0	0	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2B (Activity 2)	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Analysis	Inspectional Objectives described within the "QSIT Inspection Handbook"
Scope and nature of the process to be followed.[2]	Review and analysis of the process and qualifications of the individuals responsible for developing the QSIT objectives. Specifically, the process by which the QSIT was developed will be described in writing. The primary participants and contributors will be described and analyzed to ensure that their experiences, knowledge and skills demonstrate they are qualified to assess a quality system and determine key elements c major subsystems and their linkages. For FDA participant's this may be accomplished via a review of the individual's current C.V., resume, SF-171 or other documented evidence of their qualifications. For industr and consultants who have contributed, this analysis may be limited to a review of the individual's title and responsibilities including their representation to recognized trade or quality organizations. Overall responsibility for this activity: R. Ruff (HFR-CE350)	
Acceptance criteria (if known)	The process used to develop the QSIT provided for, considered, and implemented input from a diverse population of recognized and qualified quality professionals to ensure it focused on the key elements of a device manufacturer's quality system.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity will provide direct and objective evidenc that the inspectional focus of the QSIT is on the key elements of major quality system subsystems as determined by a diverse population of quality professionals.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity will demonstrate that th inspectional focus of QSIT is on the key elements of major quality system subsystems through a direct review of objective evidence.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome
G2B	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.

Activity #	Type of activity (test or analysis)	Parameter(s) to be measured
2	Analysis	Inspectional Objectives described with the "QSIT Inspection Handbook"

Acceptance Criteria

The process used to develop the QSIT provided for, considered, and implemented input from a diverse population of recognized and qualified quality professionals to ensure it focused on the key elements of a device manufacturer's quality system.

Summary of Results

Attachment #'s 1A-1I are summaries of the qualifications of the FDA representatives to the QSIT development team. Provided below is a brief summary of several key considerations:

Name	Grade	Title	Duty Station	FDA Experience (yrs.)
Denise Dion	GS-13	Medical Device Expert	FDA/ORA/DEIO	14
Georgia Layloff	GS-13	Medical Device Specialist	FDA/ORA/STL	29
M. Chris Nelson	GS-13	Quality Systems Expert	FDA/CDRH/OC	9
Robert Ruff	GS-13	Medical Device Specialist	FDA/ORA/NWJ-DO	9
Kim Trautman	GS-15	GMP & Quality Systems Expert	FDA/CDRH/OC	8
Cory Tylka	GS-13	CSO (medical lasers)	FDA/CDRH/OC	19
Tim Wells	GS-14	Chief, Ob-Gyn, Reengr. Team Ldr.	FDA/CDRH/OC	23
Norm Wong	GS-14	Medical Device National Expert	FDA/ORA/DEIO	27
Allen Wynn	GS-13	CSO (Field Programs Branch)	FDA/CDRH/OC	22

Attachment 2 is a photocopy of a list of members and guests of FDLI's Ad Hoc Group for Quality System Inspections. This group represented a number of medical device manufacturers, trade organizations and consultants to the medical device industry and contributed on several occasions to the QSIT development project. Provided below is a summary of titles of members of the FDLI group:

V.P., Manager of Compliance
V.P., Global Quality Management
Principal (Consultant)
Executive Director (Consultant)
Director, Regulatory Compliance and Audit
Dir. of Continuous Improvement and Quality Systems
Dir. of Technology and Reg. Affairs (Trade Org.)
Ex. V.P. (Consultant)
V.P., Compliance & Quality Systems (Consultant)
Manager, Corporate Compliance
Quality Systems Champion
Dir. Research & Development
Special Counsel (Trade Org.)
Regulatory Affairs and Compliance Manager
Reg. Staff Manager, Med. Products Group

Attachment 3 is a summary of the QSIT development history. Attachment 3 documents that in addition to seeking input from the above referenced individual's, the QSIT development team sought input from the publi during an open public meeting and FDA medical device investigators representing a variety of experience levels.

Conclusion

The findings do [X] do not [ ] meet the acceptance criteria for this activity.

Additional Comments

Activity Champion(s) Robert G. Ruff, CSO (HFR-CE350)

Cc:
Bcc:
From: Denise Dion@DEIO@FDAORAHQ
Subject: BIO
Date: Tuesday, March 2, 1999 at 2:08:06 pm EST
Attach:
Certify: N

Education: Associate Degree - Emergency Medicine
Bachelor of Science: Biology (Co-ordinate major in Environmental Studies, Chemistry minor, Pre-Medical Curriculum)
Post-Graduate Masters Courses - Aquatic Ecology, Genetics, Microbiology

FDA History:

Investigator GS 7, 9, 11 - Detroit District 1985-1990
Investigator, GS-12 Biologics Specialist - Detroit District, 1990-1991
Investigator, GS-13 Regional Biologics Specialist - Dallas District, 1992-1994
Investigator, GS-13 Medical Device Expert - Division of Emergency and Investigational Operations, 1994-present

In current position, develops agency policy and procedures relative to the inspection and investigation of medical device establishments. Acts as expert resource for agency personnel relative to the inspection and investigation, etc. of medical device establishments. Performs high level inspection and investigations of medical device establishments.

Let me know how much more you really need.

Denise D. Dion
DEIO - Medical Device Group
) 827-5645

Georgia A. Layloff

FDA/St. Louis Branch Office
12 Sunnen Drive
Suite 122
St. Louis, MO 63143

Phone: 314-645-1167 x 121
email: glayloff@ora.fda.gov
Fax: 314-645-2969

EXPERIENCE

Investigator, St. Louis, MO — 1980 - Present

- Currently serves as a regional field expert in the area of medical devices. Expertise includes design control and premarket approval investigations, quality systems, and case development activities. Previously served as a medical device specialist (1993-1997) and also a journeyman investigator (1980-1993).
- Core member of the QSIT Team making significant contributions to all aspects of the project including development of the Handbook and CD computer based training. Subteam leader for the 6/98 Open Public Meeting. Co-subteam leader for the QSIT Study including training of field investigators and compliance officers participating in the Study. Co-subteam leader for the QSIT Validation project.
- Contributing member of the Design Control Inspectional Strategy Team which developed the strategies being utilized by FDA investigators in assessing compliance to design controls under the Quality System Regulation.
- Served as a member of the Audit Development CADRE that developed the specific criteria that is being used during the performance audits of FDA candidates for Level II medical device certification.
- Achieved Level II medical device certification and is also an active certification performance auditor.
- Consults and provides technical assistance to FDA management and staff including the Office of Criminal Investigations, and also industry representatives.
- Overall investigative activities have resulted in millions of dollars of voluntary industry corrections. Resulting legal actions have included prosecutions.
- Monitors and coordinates medical device program accomplishments and prepares workplans.
- Member of an FDA/industry team that designed the "Facilitating Effective Interaction" workshop and contributor to the resource guide for conducting such a workshop.
- Reviewed and evaluated domestic and foreign design control inspectional reports.
- Conducted undercover assignments.
- Organized and facilitated workshops and training sessions.
- Served as a subject matter expert to a Course Advisory Group for FDA's Basic Medical Device Course.
- Coordinated recall and emergency, registration and consumer complaint activities.

Investigator, Philadelphia, PA — 1977 - 1980

- Served as a journeyman investigator. Evaluated industry compliance while conducting complex medical device, including IVD, human and veterinary drug, and food inspections, investigations and sample collections. These included areas such as GMPs, sterility, bioresearch monitoring, fraud, pre and post award government purchase acceptances, product defect reports involving deaths and serious injuries and product recalls.
- Analyzed investigational results to determine assignment termination time and follow-up action.
- Voluntary industry corrections resulting from inspectional activities included the extension of a device recall to include over $1 million of product, and the initiation of a Class I device recall.
- Legal and administrative actions resulting from inspectional activities included product seizures and the issuance of Regulatory and Notice of Adverse Findings letters.
- Consulted and assisted compliance officers in case preparations.
- Issued and monitored inspectional assignments.
- Reorganized, updated and monitored registrations.

Chemist, Philadelphia, PA — 1970 - 1977

- Achieved the level of journeyman chemist.
- Conducted research in laboratory automation including system design and setup, and direct on-line interfacing, data acquisition and operation of multi-instrument/computer systems. Published findings and converted such systems to operational use.
- Served as analytical group leader.
- Served as Laboratory Management Systems Coordinator and Laboratory Computer System liaison within the district and with headquarters.
- Designed, developed and published analytical methods for autoanalyzers.

- Conducted method development, validation, and analyses of samples covering a wide range of regulated commodities.
- Performed check analyses on violative samples, NDA methods validations, collaborative studies, and National QA samples.
- Reviewed, evaluated and made recommendations regarding the reliability and accuracy of methods used by industry.
- Consulted and advised compliance officers and investigators.
- Monitored compliance programs.
- Evaluated and recommended the purchase of instrumentation systems and equipment.

TRAINING

(Given) Provided on-the-job training to FDA personnel. Made presentations to FDA and industry at local, district, regional, and national meetings and workshops sponsored by FDA and trade/professional organizations.

(Received) Significant courses have involved FDA laws, regulations and policies, investigative/auditing techniques, validation, quality assurance, computer systems, supervision, communications, and self-directed work teams.

FORMAL TEMPORARY ASSIGNMENTS (DETAILS)

- Compliance Officer
- Office of Regulatory Affairs (ORA-21) Staff (Headquarters - Field)
- Consumer Safety Officer (Headquarters - Medical Devices)
- Program Analyst (Headquarters - Foods)
- Supervisory Investigator
- Recall and Emergency Coordinator
- Complaint Coordinator
- Registration Monitor
- Government Wide Quality Assurance Program Coordinator
- Supervisory Chemist
- Laboratory Research Coordinator

AWARDS

- Recognitions for significant contributions in furthering the Agency's partnership goals with the medical device industry including four team Hammer awards from Vice President Gore's National Performance Review.
- FDA Outstanding Achievement Award (1998)
- FDA Group Award of Merit for extraordinary commitment, creativity, and effective development of the criteria necessary for the audit requirements of ORA's Investigator Performance Certification Program (1998).
- CDRH Cash Award for outstanding performance in the development and implementation of the design control aspects of the Quality System Regulation (1998).
- CDRH Cash and Time Off Awards for outstanding contributions made during the Center-wide organizational transformation effort to transform Center processes (1998).
- Other special recognitions include Outstanding Performance Awards, District Honor Roll Membership, FDA Commendable Service Award, Commissioners' Special Citations, FDA Award of Merit (Group), employee suggestion awards, special act and service awards, and various headquarters, regional and district commendations for outstanding work performance and quality, professionalism, competency, training skills, diligence, knowledge, taking charge of situations, use of good judgement, cooperation, altruism, quick grasp of complex issues, conscientiousness, congeniality, and dedication to duty.

AFFILIATIONS

Memberships include ASQ (Biomedical Division), and AFDO.

EDUCATION

BS degree in Chemistry from College Misericordia, Dallas, PA

RESUME

Name: Christine Nelson
Address: Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health
2094 Gaither Road
Rockville, MD 20850
Phone: 301-594-4611, ext. 134

February 1995 to present: Consumer Safety Officer and Quality Systems Expert for the Office of Compliance
As a Consumer Safety Officer and Quality Systems Expert, I:

- Provide guidance and training to FDA and industry on the Quality System Regulation and the Electronic Records and Electronic Signatures Regulation;
- Participate in implementation of the Mutual Recognition Agreement between the US FDA and the European Union – in particular the auditing part of the MRA;
- Participate in development and implementation of a new approach to inspecting medical device manufacturers, the Quality System Inspection Technique;
- Represent the Center for Devices and Radiological Health (CDRH) and participate in the Global Harmonization Task Force's Study Group 4 – Auditing;
- Participate in the development of a proposed rule on Good Tissue Practices for tissues and cellular-based products with the Center for Biologics Evaluation and Research;
- Represent CDRH and participate in FDA's program for level II certification of device investigators;
- Represent CDRH and participate in FDA's working group to develop guidance and training in the Electronic Records and Electronic Signatures Working Group.

May 1993-February 1995: Acting Branch Chief, OB/GYN and Therapeutic Radiation Branch, Division of Enforcement II, Office of Compliance, CDRH.
As Acting Branch Chief, I:

- supervised employees and reviewed their work, including GMP reviews, Warning Letters, and other regulatory action recommendations;
- and provided guidance and training including GMP guidance.

July 1990 to May 1993: Consumer Safety Officer, Manufacturing Quality Assurance Branch, Division of Compliance Programs, Office of Compliance, CDRH
As a Consumer Safety Officer, I:

- Reviewed establishment inspection reports submitted for foreign device manufacturers and for domestic device manufacturers as part of regulatory actions;
- Identified the appropriate GMP regulatory cites to address GMP objectionable conditions, evaluated supporting documentation for adequacy, and provided an overall evaluation of the state of control and compliance in support of regulatory actions;
- Drafted Warning Letters for foreign firms, and evaluated their replies, and drafted responses letters to them;
- Provided support for three major injunctions including a corporate-wide injunction.

September 1977 - July 1990: Compliance Officer, Office of Compliance and Administrative Litigation, US Consumer Product Safety Commission.
As Compliance Officer I:

- Provided advice, guidance and training to CPSC and industry on product safety regulations;
- Provided support for legal actions including seizures and injunctions;
- Developed and monitored compliance programs.

December 1975 – September 1977: Public Health Analyst, Office of Epidemiology, US Consumer Product Safety Commission.
As Publish Health Analyst, I:

- Analyzed injury and death data to identify hazard patterns associated with consumer products.

June 1974 – December 1975: Consumer Safety Officer, New Orleans Area Office, US Consumer Product Safety Commission.
As Consumer Safety Officer, I:

- Inspected manufacturers, distributors and retailers to check compliance with CPSC regulations for consumer products;
- Investigated accidents, injuries and deaths to explore the role of consumer products in the incidents.

Education:
Northern Illinois University, DeKalb, IL – Bachelor of Science
University of Illinois, Champaign/Urbana, IL – Master of Science

Memberships:

- Association for the Advancement of Medical Instrumentation (AAMI)
- American Society for Quality (ASQ)

Achievements and Awards:

- American Society for Quality Certified Quality Auditor
- Recognition of Technical Assistance to Israel for which FDA received the Ronald H. Brown Award, 1996
- FDA Commendable Service Award, 1997
- CDRH Special Recognition Awards, 1995, 1996, 1997, 1998
- FDA Group Recognition Awards, 1994, 1995, 1998
- CDRH Employee of the Month, 1997

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EDUCATION AND TRAINING:

B.S., Biology, June 1983
Lincoln Memorial University, Harrogate, TN

- Alpha Chi National Honor Society
- Dean's List

Completed or instructed at FDA and industry sponsored national and regional training, including:

- Six Month Basic Investigators' Training
- Basic Food & Drug Law and Evidence Development
- The Reid Technique of Specialized Interviewing
- Introduction to Medical Devices
- Intermediate Medical Devices Plastics
- Medical Device Process Validation (faculty)
- Industrial Sterilization for Drugs and Devices
- Computer System Validation
- Introduction to International Inspections
- Sterilization Issues for Medical Device Inspections (Regional)
- Medical Device Electronics (Regional)
- Medical Device Plastics (faculty, Regional)
- Quality Audits for Improved Performance (ASQC)

CERTIFICATION:

Level II Certified Medical Device Investigator and Performance Auditor

QUALIFICATIONS AND EXPERIENCE:

- Six years of Medical Device Industry Experience
- Eight years experience with FDA (currently, GS-13/4 Medical Device Specialist)
- Eight foreign inspection campaigns to date (outcomes from NN to AA, W/L w/Auto Detention)
- Member, Medical Device Certification Audit Development Cadre
- Member, Design Control Inspectional Strategy Team
- Member, CDRH Reengineering Team (Reengineering the Medical Device Inspectional Process)
- Faculty Member, AAMI "GMP Requirements and Industry Practice" (Quality System Course)
- Faculty Member, AAMI "Design Control Requirements and Industry Practice"
- Faculty Member, National Course on Medical Device Process Validation
- Faculty Member, Technical Advisor to Central Region Training Branch (Medical Device Training)
- New Jersey District Medical Device Cadre Facilitator
- Recruited to provide technical and investigational support to OCI NYFO
- Presented at local, national and international medical device conferences, workshops, etc.
- Conducted numerous, technical medical device inspections and investigations
- Conducted Pre-op reviews and SBR site visit
- Completed details as Acting Compliance Officer and Acting Supervisory Consumer Safety Officer
- FDA Award of Merit, FDA Outstanding Achievement Award, numerous letters of Commendation and Appreciation

Kimberly A. Trautman draws on her experience with FDA as the Center for Devices and Radiological Health (CDRH) expert on Good Manufacturing Practices (GMPs) and Quality Systems. In addition to writing the 1996 final rule and the 1995 working draft of the quality system regulation and preamble, she also reviews inspection reports of foreign and domestic medical device manufacturers to identify violations of the GMP regulations and provides guidance to FDA field investigators and the medical device industry. She is a member of the Global Harmonization Task Force, is a representative to the U.S. Technical Advisory Group (TAG) to ISO/TC 176 and ASQC Z-1/TG 11 Quality Assurance Committee, is the U.S. delegate to ISO/TC 210, and is the ISO TAG to TC 210 Working Group 1 Co-chair.

Trautman has taught at medical device training courses and prior to her current position was a patent examiner specializing in medical devices. She received an MS degree in biomedical engineering from the University of Virginia and a BS degree in molecular and cell biology from the Pennsylvania State University. She is a member of ASQC and the Association for the Advancement of Medical Instrumentation.

Record to the File – Employee Experience Record Date: 2/17/99

Employee: Corinne Tylka
Consumer Safety Officer, GS-13/7

Office: Office of Compliance, DOEI/GSDB
Center for Devices & Radiological Health
2098 Gaither Rd. (HFZ-323)
Rockville, MD 20850

Phone: 301-594-4595, ext. 170

Education: Bachelor of Science degree in physics, Penn State 1974-1977

Employment: 1977-1981 – FDA Bureau of Radiological Health, physicist GS-5

Work description: lab instrumentation, noncoherent light source and laser measurements, instrument calibrations in support of FDA/BRH field laser inspection programs

1981-1984 – housewife, unemployed in Hamburg, Germany

1984-1993– FDA/CDRH Office of Compliance, Div. of Electronic Products

Work description: Consumer Safety Officer - regulation of medical and nonmedical laser manufacturers under the Federal laser product performance standard. Report reviews, 5-10 laser manufacturer inspections per year.

On-the-job training: Grad. Courses at U. MD: Optics, Quantum Mechanics, Complex Variables
Basic Food, Drug, & Law course
Medical Device Updates
Radiation Physics Course, Boston 1987
Numerous in-house computer training courses

1993-present – FDA/CDRH Office of Compliance, Div. Of Enforcement I, General Surgery Devices Branch

Work description: Consumer Safety Officer - regulation of medical laser manufacturers under the Federal laser product performance standard via Laser Product Report reviews, communication with industry. In addition, reviews of GMP and quality systems inspections, 510(k)s, IDEs, PMAs, device labeling issues, recalls, legal actions

Training: Numerous in-house Office-wide GMP training, Quality Systems reg., Design Controls, Med. device software safety
Numerous in-house computer training courses

Conference-American Society of Lasers in Medicine & Surgery
(Toronto) 1994
IEC 601 training 1996
AAMI GMP Requirements & Industry Practice 1997
Electromagnetic Compatibility/Electromagnetic Interference 1997
CDRH - Medical Device Polymers 1998
CDRH – Medical Device Biomaterials 1998

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EXPERIENCE

Team Leader, Quality Systems Inspection Reengineering Team, FDA, Center for Devices and Radiological Health (CDRH)	1997-1999
Chief, Ob-Gyn, Gastroenterology and Urology Device Branch, Division of Enforcement II, Office of Compliance, FDA, CDRH	1990-1993
Chief, Product Evaluation Branch II, (MDR group) Division of Product Surveillance Office of Compliance & Surveillance, FDA, CDRH	1990-1993
Executive Development Program, Office of Personnel Management, Washington, DC, temporary positions included Acting Director of Investigations, Baltimore District, FDA Commissioner's Executive Office staff, FDA Office of International Affairs, and others	1989-1990
Consumer Safety Officer, Import Operations Branch, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs (ORA) FDA, Rockville, MD	1987-1989
FDA Regional Small Business Representative, Atlanta Region, ORA, Atlanta, GA	1981-1987
FDA Field Investigator, Waukegan Resident Post, Chicago District, ORA, Waukegan, IL	1977-1981
FDA Field Investigator, Chicago District Office, ORA, Chicago, IL	1976-1977

ACOMPLISHMENTS RELATED TO QUALITY SYSTEM REENGINEERING

As Team Leader, Quality Systems Inspection Reengineering Team, CDRH, I have managed all aspects of the reengineering effort. Some of the activities include benchmarking, evaluating the present program, making change proposals and implementing all aspects of the proposal. I manage at least seven sub-teams consisting of quality system experts and professionals with expertise in enforcement, inspections, and other areas. Sub-team projects include the creation of the QSIT Handbook, development of a new Compliance Program for quality systems inspections, development of a training course for field investigators covering the new inspection technique, managing a pilot inspection program, which involves three districts, managing an evaluation program, managing a web site, handling interactions with field management, reengineering steering committee, CDRH management, industry, the public and the media.

As Chief, Ob-Gyn, Gastroenterology and Urology Device Branch, Division of Enforcement II, CDRH, I am responsible for all aspects of enforcement that involve firms in this product area, (which includes such products as condoms and dialysis devices). I am involved in both issuances of assignments to inspect foreign and domestic device firms, and the review of the findings from inspections, as well as other legal matters. I oversee review of all violative foreign inspection reports that fall in this product area, and develop and issue warning letters and other correspondence related to those inspections. I also manage domestic legal actions, such as injunctions, related to quality system violations that involve firms in this product area, and consult with district officials on issues related to quality system inspections. I managed the Center's largest corporate wide injunction project involving quality system violations.

As Chief, Product Evaluation Branch II, Division of Product Surveillance, CDRH, I contributed some content material to the Quality System Regulation, when it was being drafted in 1993. As chief of one of the two MDR branches, I frequently issued assignments to district offices covering device problems, and supervised numerous activities related to device problems. I was involved in follow-up activities related to device problems, such as recalls, press releases, device testing, and coordination with other agencies.

As Acting Director of Investigations in Baltimore District, I was responsible for all investigation and inspection in the three-state area. During my tenure I supervised several aspects of the generic drug investigations; an action that eventually resulted in large fines and jail time for corporate individuals.

As Consumer Safety Officer, Import Operations Branch, Division of Field Investigations, I was responsible for numerous aspects of the national import program. Specifically, I managed the training courses for all FDA's import inspectors and managers, as well as national import conferences.

As Small Business Representative, Atlanta Region, I was involved in providing technical assistance to firms regulated by FDA. The assistance included on-site visits, phone assistance, providing references and copies of regulations and other technical information. I developed and participated in industry workshops, primarily for the medical device industry, but also for other industries, in the eight state geographic area that comprises the southeast region. I developed much of the course content and technical material that was incorporated into DSMA's (CDRH Division of Small Manufacturers Assistance) national workshops on Good Manufacturing Practices.

As Field Investigator, Chicago District Office and Waukegan Resident Post I was involved in inspecting manufacturers, distributors, and other establishments for compliance with medical

device, drug, biologic, food and veterinary medicine requirements. During my tenure at Waukegan I was involved with inspecting some of the nation's largest pharmaceutical and device manufacturers.

OTHER ACCOMPLISHMENTS

Served formal details as Acting Deputy Director, Office of Compliance, CDRH; Acting Director Division of Product Surveillance, CDRH; Acting Deputy Director, Pacific Region.

Managed large projects, such as Commissioner Young's Action Plan II (Import Program Initiatives); spearheaded the Center Director's (Benson) Listening Group Project.

Worked on agency wide groups: was CDRH representative to FDA's Customer Service Initiative Group; represented CDRH at FDA's Compliance Policy Council.

Oversaw projects such as development of the MDR, Distributor Reporting and User Facility reporting regulation, implementation of new data systems for compilation & analysis of device problem reports, and implementation of numerous action items from the CDRH Action Plan, specifically those related to post market surveillance. Developed a new automated method to handle MDR reviews.

Was involved in the European Community (EC-1992) project in International Affairs Staff, as Acting Health Science Administrator. I prepared briefings for the Vice President, the Associate Commissioner for Health Affairs and Center Directors.

Was involved in preparing the agency's FY-90 and FY-91 budgets, as Budget Analyst in the Division of Financial Management. I helped prepare the Commissioner's testimony for the House and Senate Appropriations hearings, and briefings for the commissioner and center directors.

EDUCATION

Bachelor's Degree: Life Sciences – University of Wisconsin – Parkside, Kenosha, WI
Numerous FDA Courses involving medical devices, process validation, law, and compliance

PROFESSIONAL AFFILIATIONS

American Society for Quality, Biomedical Division and Quality Audit Division

NORMAN WONG

Norm is an Engineer and National Medical Device Expert attached to DEIO (Division of Emergency & Investigational Operations) working out of the Seattle District Office. He started working for the Agency in 1972 and in 1983 became a national expert. He has over twenty years of specialized experience in performing domestic and foreign medical device inspections. He is highly experienced in inspecting medical device manufacturing processes and medical device electronics. He serves as a technical consultant for the field operations and the Centers for Devices and Radiological Health. He also, occasionally serves as a technical consultant for the Centers for Biologics and Drugs.

He serves on the course advisory groups and is a principle instructor in basic and advance medical device courses relating to manufacturing processes, computer inspectional applications, and medical device electronics. He has provided training to Agency and outside the Agency throughout the country.

He is currently participating in CDRH reengineering projects relating to new inspectional techniques (QSIT, HACCP and DCIS), compliance action levels, and computerized training techniques. He is a member of the device certification development cadre, a performance auditor, and a member of the foreign inspection team. He is also participating in revising the ORA medical device inspectional guidance document and a number of IOM updating projects.

Norm has a BS degree in chemical engineering and years of formal and informal studies in electronics and computer software related subject areas.

ALLEN WYNN

Allen Wynn is a Consumer Safety Officer (CSO) in the Field Programs Branch (FPB), Division of Programs Operations, Office of Compliance, Center for Devices and Radiological Health (CDRH). Mr. Wynn has been with FPB since May 1993 and his responsibilities include, but not limited to, oversight of the Premarket Approval, Foreign, and Class III 510(k) Pre-Clearance programs.

Mr. Wynn has been with CDRH since May 1990, where he worked as a Good Manufacturing Practice (GMP) reviewer with the former Manufacturing Quality Assurance Branch. Responsibilities included reviewing field inspectional reports of both domestic and foreign medical device manufacturers to determine whether violations of the GMP had occurred. In addition, duties and responsibilities also included the review of Premarket Approval Applications and responding to written and verbal inquires from industry and the FDA field on the interpretation and application of GMP requirements to the manufacture of medical devices.

Mr. Wynn joined FDA in September 1977 as a CSO with the New York District Office.

Mr. Wynn has a Bachelor of Science degree in Chemistry from Elizabeth City State University, Elizabeth City, NC.

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Quality System Inspection Technique (QSIT) Development History

August 13 – 14, 1997: QSCA Development Workshop to explore HACCP for the inspection of Medical Device Manufacturers (meeting which stimulated the development of QSIT and HACCP for Medical Devices Development Projects)

January 21 – 22, 1998: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

April 16 – 17, 1998: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

May 4, 1998: FDA QSIT Development Team meeting

June 18, 1998: Quality System Inspections Open Public Meeting, comments used to revise QSIT

August 1998: Proposed QSIT provided to non-development team Novice, Intermediate and Expert Medical Device investigator's for review and comment, comments used to revise QSIT

August 17 – 21, 1998: FDA QSIT Development Team meeting

September 1998 – February 1999: QSIT Field Tested by three FDA districts, monthly phone calls on progress, test cadre input used to revise QSIT

December 7, 1998: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

January 14, 1999: FDA QSIT Development Team members participated as invited guests of FDLI Ad Hoc Group for Quality System Inspections

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G2B (Activity3)	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a question on an Evaluation Form
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT by completing an Evaluation Form for each QSIT inspection conducted during the Study. The effect of the use of QSIT in increasing inspectional focus will be determined by the following Evaluation Form question: "Did use of the QSIT result in a more focused inspection? Yes __ No __ Comments _____ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the use of QSIT resulted in a more focused inspection.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on whether use of the QSIT approach resulted in a more focused inspection.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G2B	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
3	Test	Responses by investigators to a question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the use of QSIT resulted in a more focused inspection.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the Evaluation Form question: "Did use of the QSIT result in a more focused inspection? Yes __ No __ Comments___..." A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 37 (88%) No 1 (2%) Other 4 (10%) *(3 responses were – both Yes and No and 1 response was - Not sure)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Rev. 2/12/99

Item # G2B (Activity 3)

INVESTIGATOR QSIT EVALUATION FORM question:

Did use of the QSIT result in a more focused inspection? Yes __ NO __ Comments ____

TABULATION of RESPONSES

Inspection Code	Yes	No	Other	Comment	*
1A1	X			Yes – a different type of focus	B
1A2	X			More focused in these 4 areas.	B
1A3	X				B
1A4	X				B
1B1	X			However, I would have dug deeper in this firm if I wasn't following QSIT.	B
1B2	X			It gave me a very directed approach & made me focus on certain process & not try to cover them all.	B
1B3	X			I was very focused on the areas I reviewed.	B
1C1	X			I think I was more focused on the four subsystems. During a regular inspection, I follow the violations to wherever it leads. I usually end up conducting a very thorough inspection. I do not feel like I have conducted a very thorough inspection using the QSIT technique. It may just take a little time to get used to using this method and I may very well may have conducted a very thorough inspection. I feel more comfortable with conducting a thorough inspection using the bottom up approach.	A
1C2	X			I am not sure how long this inspection would have taken if conducted using the regular method of inspection. I'm sure it would have taken longer, but most likely with the same result.	A
1C3	X			I find that when I use the traditional method of inspection, I find more deficiencies, because I look at more of everything (SOPs, DHRs, etc.) With QSIT, I still find deficiencies, but not as much as I would using the traditional method.	A
1C4	X			I'm not sure if a focused inspection was the right type of inspection to perform for this firm. I think I would have found more deviations if I had performed a regular type of inspection. I found that I was fighting to keep to the agenda. I wanted to deviate from QSIT to follow suspected problems. If I had more time to conduct this inspection, I would have followed moew leads and I'm sure, I would have found more deviations. I think the corrective and preventative action subsystem was cheated by utilizing this subsystem. I just needed more time to adequately cover this subsystem.	A
1D1	X			I still struggled with knowing when to say when and fought the urge to do more. I also found a little rushed at times, and believe I could have done a better job preparing the 483.	C
1D2	X			This is especially true of the management responsibility section.	C
1D3	X				C
1D4	X				C
2A1		X		It is difficult to see the difference in this inspection. Firm did not have many of the required procedures.	A

Inspection Code	Yes	No	Other	Comment	*
2B1			Yes and No	QSIT tools helped to focus on and complete all aspects of the QSIT requirements. Following the prescriptive requirements of QSIT, while systematic, was sometimes contrary to the natural flow of this inspection. Resulted in a need to track multiple open issues and return to them later–this caused some re-review	C
2B2	X			In part, particularly in getting started and for general review but was less useful in areas when problems were encountered.	C
2B3	X			It does define a focus, but the sequence of review does not always fit the natural flow.	C
2C1	X			The format of the handbook kept the inspection focused.	C
2C2	X			I stayed with the QSIT booklet format.	C
2C3	X			QSIT Handbook was the most useful – it helps structure the course of the inspection.	C
2C4	X				C
2D1			Yes and No	Yes – more focused on systems & written procedures No – less focused on implementation of procedures	B
2D2	X			On systems, less focus on products/issues	B
2D3			Yes and No	Time & systems – Yes; Product problems – No	B
2D4	X			On systems (Less focused on products & performance)	B
3A1	X				C
3A2	X				C
3A3	X				C
3A4	X			Firm's representative knew exactly where the inspection was going and for the most part, was able to gather requested documents/information on personnel available for the next section. They all had a copy of the QSIT handbook (e.g. covering design controls).	C
3B1	X			This was a PMA inspection where no PMA device has been manufactured for commercial distribution. The EI's emphasis was on their various procedures and on all the validations performed. As such I was not able to utilize the QSIT system to its fullest capabilities. However, the use of the QSIT system enabled a dynamic operative system to control the focus. During the EI, it was also used to perform an artificial inspection to determine how it would assist me if a non-PMA EI was being performed.	C
3B2	X			Especially more focused under Management Controls & CAPA.	C
3B3	X			Objectionable condition coverage was focused without expanding more time in reviewing records beyond the number of records chosen for review.	C
3B4	X			Definitely. Each subsystem was covered thoroughly in a reasonable amount of time for the firm being inspected.	C
3C1	X				B
3C2	X				B
3C3	X				B
3C4	X				B
3D1			Not sure		A
3D2	X				A
3D3	X				A
Total	37	1	4		

* Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years